

Remarks/Arguments

I faxed and called the Examiner on September 17th, 2008 to discuss a suggested restriction. The Examiner call me back on September 18th, 2008 to inform me that he had no authority to make decisions by phone. Consideration of a suggested restriction as provided herein was discussed. No particular actions were agreed to.

We hereby Elected Group V with traverse.

Claims 1 and 15 have been withdrawn in reply to the restriction requirement.

We disagree with the Examiner's statements regarding unity of invention and request that the Examiner reconsider the restriction between Groups I to XII.

We hereby elect the species 3-[3,3-Dimethyl-4-oxo-4-(azabicyclo[2.2.1]heptan-7-yl)butyl]-4-[2-{4-(morpholin-4-ylcarbonyl)piperidin-1-yl}ethyl]-5-(3,5-dimethylphenyl)-1H-pyrrole as provide in Example 1.

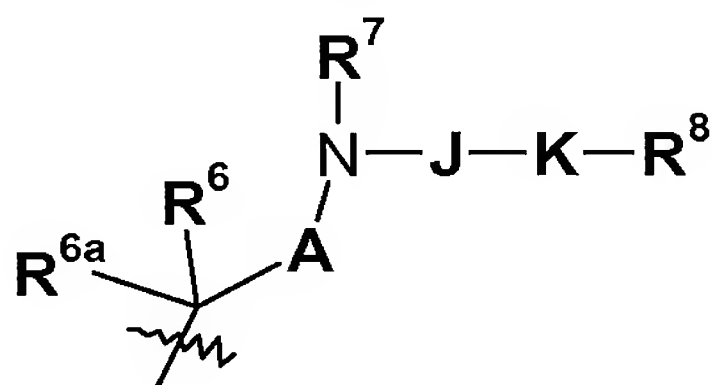
Pending Claims 2, 3, 5-11, 13, 14, 16, 19, 20 read on the elected species as provided below:

Claim 2

R¹ is hydrogen

R² is 3,5-dimethylphenyl

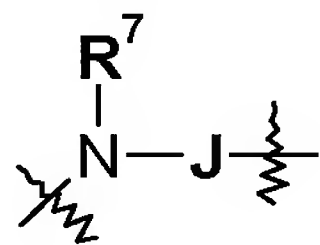
R³ is Formula IId in which



R⁶ is hydrogen

R^{6a} is hydrogen

A is methylene, i.e., -CH₂-



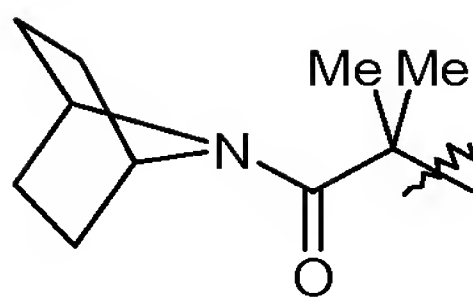
the group together forms an piperdiny ring

K is-(CH₂)_{s1}-C(O)-(CH₂)_{s2}- wherein s1 = 0 and s2 = 0

R⁸ is a morpholinyl

R⁴ is hydrogen

M is ethylene, -CH₂CH₂-



R⁵ is a group of Formula

Claim 3

A is methylene, i.e., -CH₂-

Claim 5

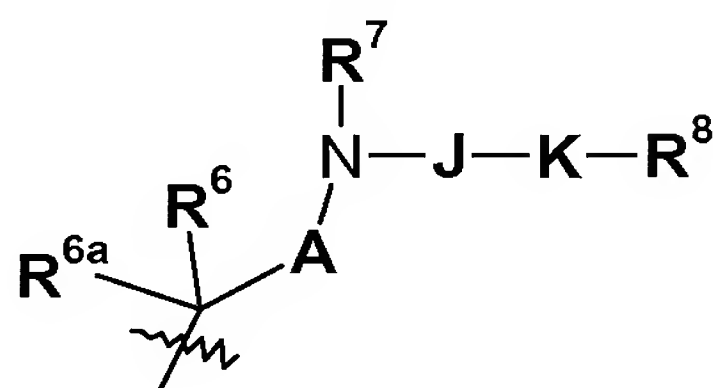
R¹ is hydrogen

Claim 6

R² is 3,5-dimethylphenyl

Claim 7

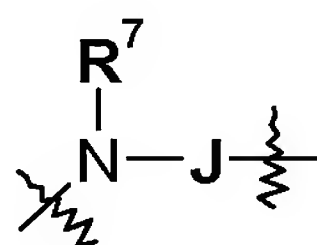
R³ is Formula IId in which



R⁶ is hydrogen

R^{6a} is hydrogen

A is methylene, i.e., -CH₂-



the group together forms an piperdiny ring

K is -(CH₂)_{s1}-C(O)-(CH₂)_{s2}- wherein s1 = 0 and s2 = 0

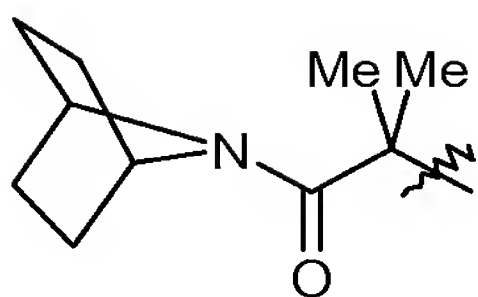
R⁸ is a morpholinyl

Claim 8

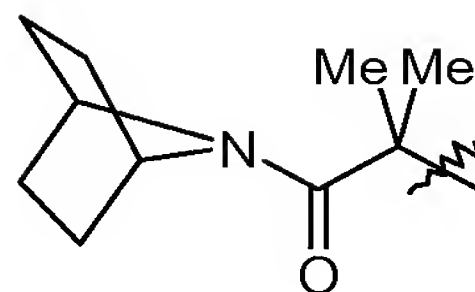
R⁴ is hydrogen

Claim 9

Formula III-a is R¹⁶ is methyl, R^{16a} is methyl and R¹⁴ and R¹⁵ form together azabicyclo[2.2.1] heptanyl.

Claims 10

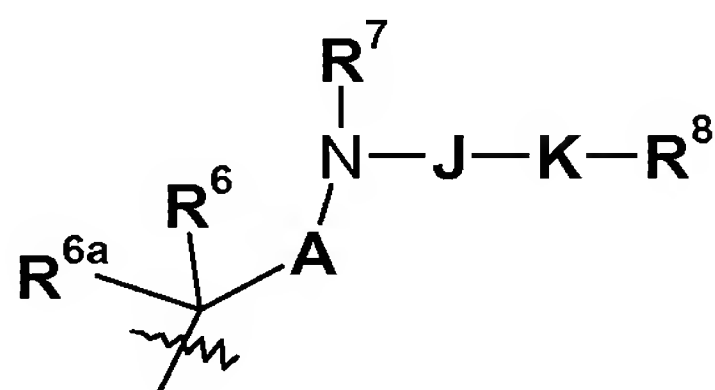
R^5 is a group of formula

Claim 11

M is $-\text{CH}^2\text{CH}_2-$

Claim 13

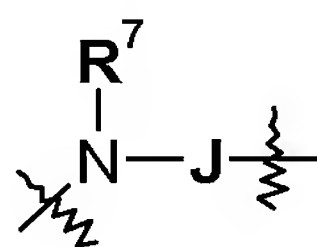
R^3 is Formula IIId in which



R^6 is hydrogen

R^{6a} is hydrogen

A is methylene, i.e., $-\text{CH}_2-$



the group together forms an piperdiny ring

K is $-(\text{CH}_2)_{s1}-\text{C}(\text{O})-(\text{CH}_2)_{s2}-$ wherein $s1 = 0$ and $s2 = 0$

R^8 is a morpholinyl

Claim 14

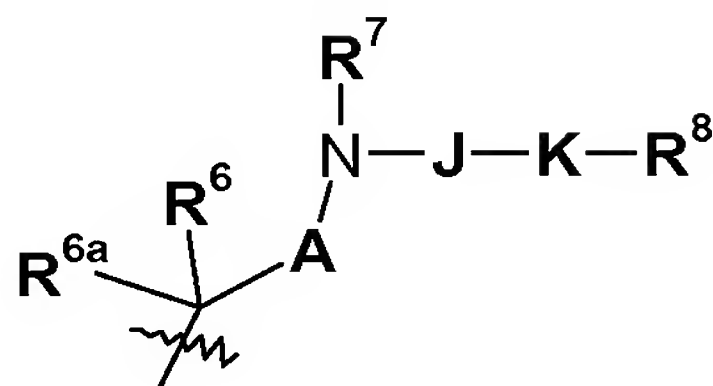
3-[3,3-Dimethyl-4-oxo-4-(azabicyclo[2.2.1]heptan-7-yl)butyl]-4-[2-{4-(morpholin-4-ylcarbonyl)piperidin-1-yl}ethyl]-5-(3,5-dimethylphenyl)-1H-pyrrole

Claim 19

R^1 is hydrogen

R^2 is 3,5-dimethylphenyl

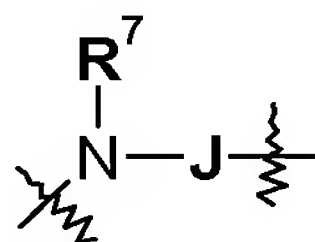
R³ is Formula IIId in which



R⁶ is hydrogen

R^{6a} is hydrogen

A is methylene, i.e., -CH₂-



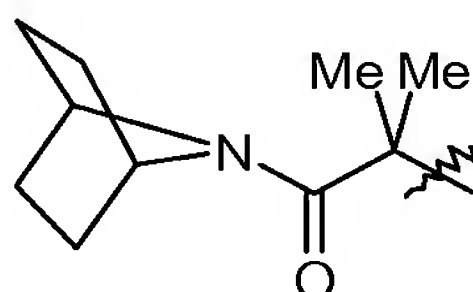
the group together forms an piperdinyl ring

K is-(CH₂)_{s1}-C(O)-(CH₂)_{s2}- wherein s1 = 0 and s2 = 0

R⁸ is a morpholinyl

R⁴ is hydrogen

M is ethylene, -CH₂CH₂-



R⁵ is a group of Formula

Claims 16 and 20

Dependent on 2 and 19 respectively

The above has been provided in order to in good faith comply with the Examiner's requests. Should the Examiner believe further clarification is needed, we request that the Examiner contact me by phone at the number provided herein.

Unity of invention exists with regard to the original and pending claims. "Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step." 37 CFR 1.475 Unity of Invention Before the International Searching Authority, the International Preliminary Examining Authority and **During the National Stage.**" (emphasis added). However, "[w]hen the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled: (A) All alternatives have a common property or activity; and (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives." MPEP 1850 III.B. Markush Practice.

With regard to Claim 1, the Examiner argues that Group I inventions do not present a contribution over the prior art since Kawai et al. (hereinafter Kawai) anticipates Claim 1. We disagree. Unity of invention exists for the original and pending claims because, as a group, the compounds make a contribution over the prior art, i.e., the compounds have common structural attributes and have gonadotropin releasing hormone (GnRH) activity.

The Examiner argues that Kawai anticipates Claim 1 because the claim 1 in Kawai overlaps in subject matter with the instant Claim 1. We disagree. The Examiner has cited no law, rule, or regulation suggesting that the mere existence of some overlapping disclosure is sufficient for anticipation. Anticipation requires that the reference disclose the claimed invention and all its elements. The courts have long held that mere overlapping generic disclosure is not anticipatory. In *re* Petering, the court held

The compounds encompassed by these claims, reciting as all of them do an ethyl group, C(2)H(5), at the 6-position or ethyl groups at the 6- and 7-positions, are not included in the limited class which we find in Karrer. Therefore, it is our opinion that these compounds have not been described by Karrer within the meaning of 35 U.S.C. 102(b) 301 F.2d 676 (1962)

Anticipation of a generic claim may be provided by the disclosure of a species of the genus within the reference. The Examiner has pointed to no such species. "A generic claim cannot be allowed to an Applicant if the prior art discloses a species falling within the claimed genus.' The species in that case will anticipate the genus." MPEP 2131.02 Genus-species situations, citing *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960). Kawai provides no such compound.

Specifically with regard to claim 14, the Examiner provides no specific reason for a lack of unity of invention. Kawai is not anticipatory. The instant claim 14 presents similar issues to those presented in, *In re Arkley*, where the court held:

[F]or the instant rejection under 35 USC 102(e) to have been proper, the Flynn reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *In re Arkley*, 455 F.2d 586 (1972)

Finally, we would like to submit to the Examiner that any restriction requirement that forces one to amend a description of a claim is improper, as it is in fact a rejection in the form of a refusal to examine what the Applicant believes to be the invention. We request reconsideration. The statements in 37 CFR 1.475(e) and PCT rule 13.3 are invalid as in violation of 35 USC Section 112, second paragraph because that Applicant is allowed to distinctly claim the subject matter the applicant regards as his invention. Please consider the

arguments provided by Justice Rich in the Concurring Opinion of *In re Weber* with regard to 35 USC Section 121 applicable hereto:

"[I]nventions are claimed," has connoted separate claims to separate inventions. It has no reference to generic or broad claims which "embrace" (the term used by the examiner and the board herein) or "cover" (the term used in the solicitor's brief in support of the board) two or more inventions. *Section 121* nowhere uses the words "embraced" or "covered." It says "claimed," and that I take to mean what it has always referred to in the terminology of the patent law, a "claim" or definitional paragraph which, in the words of § 112, second paragraph, is "particularly pointing out and distinctly claiming the subject matter the applicant regards as his invention." . . .

The fault in the PTO position is that it overlooks the obvious fact that almost any reasonably broad claim "embraces" or "covers" a multiplicity of inventions, in the sense of "dominating" them, which inventions might be separately patentable if and when presented in separate applications. Logically, this is not a sufficient excuse for refusing to examine a claim on its merits for compliance with 35 USC 101, 102, 103, and 112. None of those statutory sections, of course, justifies a refusal to examine. 580 F.2d 455, 1978.

Since the claimed compounds have a similarity in structure, it is unclear exactly why the Examiner believes there is an undue search burden. The Examiner has already identified what the Examiner believes to be anticipatory, itself evidence that the search burden is not undue.

In any case, the Applicant suggests a restriction to a group wherein,

R² is optionally substituted phenyl;

M is –CH₂–CH₂– or –CH=CH–; and

R⁵ contains a gem-dimethyl group adjacent to the M group.

New claims 19 and 20 have been added to exemplify embodiments. No new matter has been added. Support for the claims can be generally identified in Claim 2 and wherein,

R² is optionally substituted phenyl, one finds support in the specification at page 14, line 19;

M is –CH₂–CH₂– or –CH=CH–, one finds support in the specification at page 8, line 7; and

the formula of R⁵, one finds support in the specification at page 16, line 5.

With regard to claim 14, typos, e.g., capitalization, have been corrected, i.e., "1h" to "1H."

The fee for a one-month extension of time is provided herein. The Commissioner is hereby authorized to charge any deficiency in the fees or credit any overpayment to deposit account No. 50-3231, referencing Attorney Docket No. 101401-1P US.

Respectfully submitted,

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